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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,054	04/24/2006	Kim Bager	P71223US0	9927

136 7590 11/12/2009

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EXAMINER	
CHAPMAN, GINGER T	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
11/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,054	BAGER ET AL.	
	Examiner	Art Unit	
	Ginger T. Chapman	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 14-22* is/are pending in the application.

4a) Of the above claim(s) *1-6,9 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8,10 and 14-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 June 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. Claims 21 and 22 are added, claims 12 and 13 are canceled, claims 1-11 and 14-22 are pending in the application, claims 1-6, 9 and 11 are withdrawn from consideration as being drawn to nonelected inventions, claims 7-8, 10 and 14-22 are examined on the merits.

Drawings

2. The drawings were received on 22 June 2009. These drawings are acceptable.

Claim language interpretation

3. The examiner notes that the claim language "weld zone" refers to both the surface opposed to the surface where the weld is located and also to the surface on which the weld is located and the claim language "substantially smooth at the at least one weld zone" refers to the surface opposite to the surface which is welded.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 7, 10, 15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leisner et al (US 2003/0093042 A1).

7. With respect to claim 7, as best depicted in Figures 1 and 2a, Leisner discloses a body side mounting wafer 20 for attachment to a person and an ostomy bag 10, the wafer comprising a first part 21 having a first surface 24 (fig. 1) 200 (fig. 2a) adapted to be attached to a person and a second opposite surface 25; a second part 30 (fig. 1), 100 (fig. 2a) having a first surface 37 adapted to be attached to ostomy bag 10 and a second opposite surface 36; one or more welds, depicted but without reference characters in figs. 2c – 2f which are reproduced below for convenience, formed at one or more zones between the second surface 25 of the first part 21 and second surface 36 of the second part 30 (fig. 1); at least one or more welds extending over a first distance in a radial direction [0030].

8. Leisner discloses the claimed invention except for expressly disclosing that the welded areas are called weld zones. Leisner teaches the second surfaces of the parts are welded at locations depicted in Figures 2c – 2f, therefore the location of the welds are considered the zones of welding, i.e. weld zones.

9. Leisner, at [0008-10] provides motivation to provide an adhesive bond between the collection bag and the second part such that the adhesive bond coupling the bag to the second part will not break or peel during external forces applied to the bag when worn. As best depicted in Figures 1 and 2c-2f, reproduced below, Leisner teaches wherein the first surface 37 of the second part 30 is substantially smooth at the weld zones (between the second surface 25 of the first part 21 and the second surface 36 of the second part 30) and over a second distance extending over the zones so that the first surface 37 of the second part 30 is suitable for adhesive attachment 13, 17 [0026] to the ostomy bag 12 at the weld zones which correspond to locations at reference characters 15, 16 on part 13 in Figure 1 reproduced below, and teaches, at [0026], that the entire surface of 13 that contacts the first surface 37 of the second part 30 is coated with adhesive 17 across its entire surface and thus meets the limitation of being suitable for adhesive attachment at the weld zones:

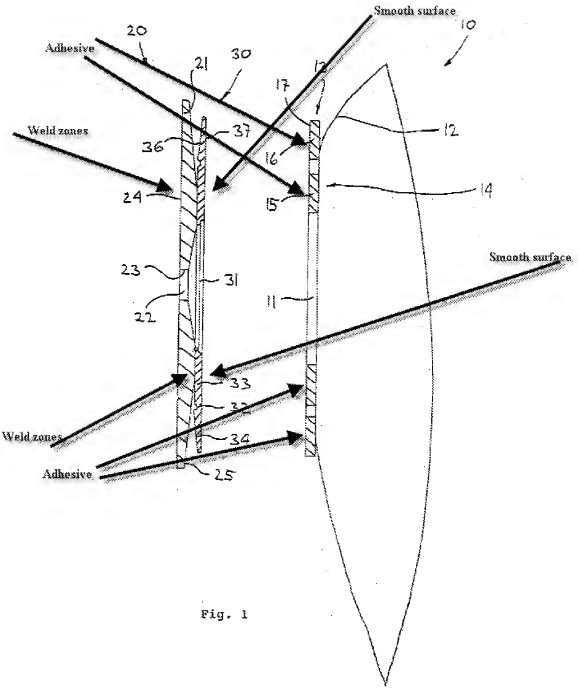
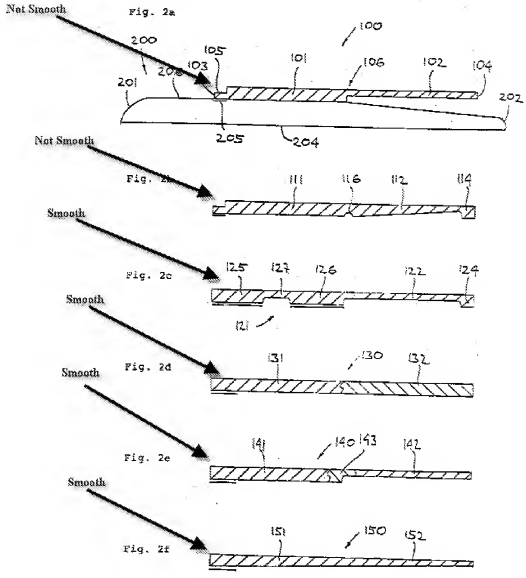


Fig. 1

10.

11. With respect to the limitation of smoothness, as best depicted in Figures 2c – 2f, reproduced below, Leisner teaches embodiments both wherein the first surface of the second part

is substantially smooth; see also figs. 2a and 2b wherein the first surface of the second part is not substantially smooth, reproduced below for convenience:



13. With respect to the limitation of the second distance extending being at least 1.5 times the first distance, as best depicted in Figures 2, Leisner teaches the second distance extends in the radial direction [0030] over ranges of distances relative to the first distance, thus disclosing the general conditions of the claim. Therefore it would have been obvious to one having ordinary skill in the art to form the second distance of the claimed value since Leisner states, at [0030], that the weld zones can be in varying distances in varying embodiments and still provide full, circumferential attachment preventing leakage.

14. One of ordinary skill in the art would recognize that a larger weld zone would result in providing a greater area of attachment at the joined portions, i.e. a more secure join, but would result in increasing the rigidity of the parts, i.e. reduce the ability of the un-welded inner portions of the parts to flex or move relative to each other. One of ordinary skill in the art would also recognize that a smaller weld zone would result in providing a less secure attachment but would reduce the rigidity of the joined parts and allow the un-welded portions of the parts to flex or move relative to each other. Therefore the distance the weld zone extends is a balance between providing a secure attachment while permitting the parts to flex or move with the movements of the wearer. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the distance of the weld zone extending the claimed distance to provide optimum securement and flexibility since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

15. With respect to claims 10 and 15, as best depicted in Figures 1 and 2a, Leisner discloses the first part 21, 200 has a first opening 22; the second part 30, 100 has a second opening 31; the zones being positioned in a vicinity of the edge 205 of the second opening [0031].

16. With respect to claim 17, as best depicted in Figure 2c, Leisner discloses multiple welds (at base of 125 and 126); the examiner notes that multiples of the same structure do not lend additional patentable weight an is an obvious modification.

17. With respect to claim 18, as best depicted in Figures 2a-2f, Leisner teaches the first part 100 having a general thickness profile [0031-2; 34-5] where the actual thickness, over the second distance deviates in a range of percentages from the general thickness of the general thickness profile over the distance, thus disclosing the general conditions of the claim, but Leisner does not specify any particular values for the deviations. Leisner teaches, at [0032, end of paragraph], that increased thickness permits improved handling during mounting and bag exchange procedures, and at [0039] that reduced thickness about the inner portion of the part in the vicinity of the opening permits the wafer to move with the stoma during the movements of the wearer. Therefore the thickness of the part along the second distance can be optimized for handling and flexibility and as such it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize these parameters. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

18. With respect to claim 19, Leisner teaches the first surface 37 of the second part 31 is adapted to form an adhesive coupling to the ostomy bag 10, and the surface is so smooth that the adhesive and a component of the bag holding the adhesive is fully capable of taking up variations of the surface from the intended shape of the surface [0026; 0008].

19. The examiner notes the use of relative and functional language in the claim and contends that the surface of Leisner is fully capable of performing the intended function.

20.

21. Claims 8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leisner et al (US 2003/0093042 A1) in view of Bager et al (WO 02/00144 A1) and further in view of Jones et al (WO 00/20157).

22. With respect to claims 8 and 20, Leisner discloses the claimed invention except for no 2 mm part of the first surface of the second part, in a cross section along the radial direction and over the second distance, has any part deviating more than 0.2 mm from a flat shape fitted to the 2 mm part. Leisner teaches embodiments, in Figures 2c - 2f, wherein the first surface of the second is substantially smooth thus providing motivation for such and disclosing the general conditions of the claim, but does not expressly disclose the smoothness does not deviate more than 0.2 mm from a flat shape.

23. Bager, at p. 18, ll. 29-31, teaches that contacting surfaces have to be brought properly in contact with each other to obtain good welds. Bager, at p. 19, ll. 22-25 and l. 30 to p. 20, ll. 1-2, provides motivation to flatten the surfaces to a flat shape in order obtain good welds and teaches, at p. 19, ll. 3-25, clamping the surfaces between rigid plate like members with resilient surfaces so as to flatten the surfaces, thus providing motivation for such. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to flatten the surfaces of Leisner as taught by Bager in order to provide flat surfaces for optimum welds since Bager states, at p. 19, ll. 23-25 and p. 20, ll. 1-2, that the benefit of flat surfaces is the flattened

surface and reduced surface variations provide proper contact between the surfaces thereby providing good welds.

24. The combination of Leisner and Bager disclose the claimed invention except for 0.2 mm. Jones, at p. 7, ll. 29-31, teaches weld zones formed between surfaces and teaches that the welding occurs at as a result of the heat generated giving melting of the plastic material up to a depth of typically 0.2 mm. Careful review of the instant Specification, in particular at ¶¶ [18-22, 23, 26 and 75] reveals no particular materials other than a body side ostomy wafer and ostomy bag welded by laser radiation. One of ordinary skill in the art would recognize that ostomy wafers and bags are generally comprised of plastic. Jones teaches welding plastic by laser radiation and that laser will weld plastic up to a depth of typically 0.2 mm and thus provides motivation for a surface with less than 0.2 mm deviation from the surface in order to provide even welding of the surface across the entire surface. In view of the teachings of Jones, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the first surface of the second part of Leisner such that no 2 mm part has a cross section deviation not more than 0.2 mm from a flat shape in order to obtain good welding across that part of the surface.

25. Claims 14, 16, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leisner et al (US 2003/0093042 A1) in view of Bager et al (WO 02/00144 A1).

26. With respect to claim 14, Leisner discloses the claimed invention except for expressly disclosing an apparatus for assembling the wafer. As best depicted in Figure 5 (p. 20, ll. 6-8), Bager teaches an apparatus for assembling a wafer including a fastening element for maintaining the parts in a predetermined abutting relationship (p. 9, ll. 12-25); and an element for providing

electromagnetic radiation to the zones to form welds (p. 12, ll. 25-33). Therefore it would have been obvious to one having ordinary skill in the art to provide an apparatus for assembling the wafer of Leisner as taught by Bager since Bager states, at p. 21, l. 11, that the benefit of using such an assembly is that it permits the area to be welded resulting in a weld.

27. With respect to claim 16, Leisner discloses the claimed invention except for the weld is a laser weld. Leisner teaches welding around the opening of the wafer, thus providing motivation for a weld around the opening [31]. Bager, at p. 7, l. 33 to p. 8, l. 8, teaches a laser weld. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the weld of Leisner as a laser weld as taught by Bager since Bager states, at p. 8, ll. 26-27, that this permits the weld to be placed with great precision at the location to be welded.

28. With respect to claim 21, Leisner discloses the claimed invention except for the first part has a first absorption coefficient at a predetermined wavelength of electromagnetic radiation; the second part has a second absorption coefficient at a predetermined wavelength of electromagnetic radiation, the first and second co-efficient being different. Leisner teaches welding the parts thus providing motivation for such but does not teach preferred means of welding. As best depicted in Figure 1a, Bager teaches a body side mounting wafer wherein a first part 1 has a first absorption coefficient and a second part 3 having a second coefficient at a predetermined wavelength and the first and second coefficients are different (p. 12, ll. 1-15; p. 13, ll.2-9). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the parts having different coefficients since this is known in the art to join parts by laser welding.

29. With respect to claim 22, Leisner discloses the claimed invention except for the lower of the first and second absorption coefficients is so low that no or insignificant melting occurs at the areas of this part through which the radiation travels toward the zones to welded, and wherein a higher of the first and second absorption coefficients is high enough to primarily absorb the radiation in the vicinity of the zones of the second surfaces in order to obtain a localized heating and not a heating through a larger extension of that part. Leisner teaches welding the parts thus providing motivation for such but does not teach preferred means of welding. As best disclosed at p. 11, ll. 26- p. 12, l. 1 and ll. 28-34 to p. 13, ll. 1-9, Bager teaches lower and higher absorption coefficients to obtaining localized heating and not heating through a larger extension. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the wafer of Leisner with the absorption coefficients as taught by Bager since Bager states, at p. 13, ll. 8-9, that this results in the formation of a weld.

Double Patenting

30. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

31. Claims 7 and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 7,244,482 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are drawn to the substantially identical structure recited in terms of the laser welded surfaces being capable of absorbing laser light.

32. Claims 7 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 34 of copending Application No. 11/578,366 (US 20080176023 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and co-pending claims are drawn to the substantially identical structure with the laser weld described in terms of the absorption coefficient of the surfaces which are welded.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

33. Claims 7 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 36 of copending Application No. 11/826,266 (US 20070262479 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and co-pending claims are drawn to the substantially identical structure with the welded surfaces described as welded layers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

34. Applicant's arguments with respect to claims 7-810 and 14-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 3761
11/04/09

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